510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name and Address of Applicant

Avinger, Inc.
400 Chesapeake Drive
Redwood City, CA 94063

B. Contact Person

Albert Boniske
Regulatory Affairs Consultant
(408) 400-0856

C. Date Prepared

January 27, 2012

D. Device Name

Trade Name:	Kittycat and Kittycat 2 Catheters
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter

E. Device Classification

Classification:	21 CFR §870.1250
Product Code:	DQY
Device Class:	Class II

F. Predicate Device

The Kittycat and Kittycat 2 Catheters are substantially equivalent to the Avinger Wildcat 6F Catheter (K111338).

G. Device Description

The Kittycat Catheters consist of a Catheter Shaft with a Handle assembly at the proximal end and a rotating Distal Tip. The Kittycat Catheters have a working length of 140 cm and 150 cm for the Kittycat and Kittycat 2, respectively. A locking Luer at the proximal provides entry to a lumen that supports and facilitates movement of a guidewire. The Kittycat Catheters have been irradiated for sterility and are intended for single-use only. The Kittycat Catheters are fundamentally the same device and only differ in handle design and Distal Tip

deflection mechanism: the Kittycat Catheter utilizes a slider-based Distal Tip deflection mechanism while the Kittycat 2 Catheter utilizes a pre-shaped Distal Tip.

H. Intended Use

The Kittycat Catheter is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention. The Kittycat Catheter is contraindicated for use in the iliac, coronary, cerebral or carotid vasculature.

The Kittycat 2 Catheter is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention. The Kittycat Catheter is contraindicated for use in the iliac, coronary, cerebral or carotid vasculature.

I. Substantial Equivalence

The Kittycat Catheters are substantially equivalent to the Avinger Wildcat 6F Catheter (K111338) and original Kittycat Catheters (K101647 and K112579). The subject and predicate devices have the same mechanism of action (manual advancement) and perform the same function (placement of guidewires beyond stenotic lesions in the peripheral vasculature). The only difference is the use of spiral flutes in the Distal Tip on the Kittycat Catheters as opposed to bilateral wedges as on the Wildcat 6F Catheter. The changes to the Wildcat 6F Catheter cleared under K111338 results in no significant changes to technological characteristics and do not raise any new issues of safety or effectiveness.

J. Non-Clinical Performance Data

The following non-clinical testing was previously conducted with the original Kittycat Catheters to support a determination of substantial equivalence to the predicate device. Tip penetration testing was performed to ensure the catheter did not advance when the tip is engaged in tissue.

• Visual and Dimensional Verification	• Spiral Blade Functional Testing
• Tensile Testing	• Coating Friction Testing
• Torque Testing	• Biocompatibility
• Guidewire advancement	• In Vitro Simulated Use Testing
• Device Advancement	• Packaging Testing

• Tip Deflection Testing	• Shipping Testing
• Device leak testing	• Shelf Life Testing
• Luer Leak Testing	• Sterility Testing
• Flexibility/Trackability	• Tip Penetration Testing

The above testing confirmed that the Kittycat Catheters performs according to the stated intended use. All data fell well within pre-determined product specifications and external standard requirements. Results of non-clinical testing demonstrated that the Kittycat Catheters are substantially equivalent to the predicate device for the stated intended use.

K. Conclusions

The Kittycat Catheters have been carefully compared to legally marketed devices with respect to intended use and technological characteristics. Non-clinical testing was conducted to validate the performance of the devices and ensure the Kittycat Catheters function as intended and meet design specifications. The comparison and non-clinical results demonstrate that the devices are substantially equivalent to the predicate device for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Avinger, Inc.
c/o Mr. Albert Boniske
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SEP 18 2013

Re: K120273
Trade/Device Name: Kittycat Catheter and Kittycat 2 Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: January 27, 2012
Received: January 30, 2012

Dear Mr. Boniske:

This letter corrects our substantially equivalent letter of March 30, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K K120273

Device Name: Kittycat 2 Catheter

Indications for Use:

The Kittycat 2 Catheter is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention. The Kittycat Catheter is contraindicated for use in the iliac, coronary, cerebral or carotid vasculature.

Prescription Use X **Or** **Over-The-Counter Use** _____

(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120273